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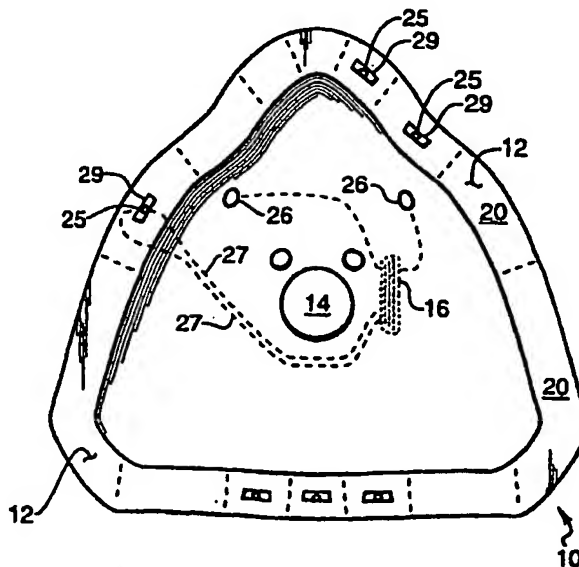
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(54) Title: BIO-MASK WITH INTEGRAL SENSORS

(57) Abstract: A breathing mask (10) for use in monitoring a patient, providing sensors (25, 26) built into the mask (10) for ease of application to a patient such that donning the mask (10) places all the required sensors on the patient. The mask (10) has a perimeter (12) with a soft pliable material with sensors (25) therein for contacting the patient's skin and making an airtight seal. The mask (10) also has sensors (26) on the body of the mask and on associated straps or caps. The sensors (25, 26) can be used for monitoring the patient's EMG, EEG, EOG, ECG, surface blood pressure, temperature, pulse, blood oxygen, position of the patient, activity level of the patient, sounds and gas pressure in the mask (10).

1

2   "Biomask with Integral Sensors"

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6   Background of the Invention

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8   Field of the Invention

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10   This invention relates to a breathing mask with built in sensors for monitoring

11   patients with sleep apnea, breathing disorders for use during anesthesia or ventilation

12   support.

13

14   Description of the Related Art

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16   Masks such as shown in patent 5,243,971 for applying a positive pressure to

17   patients with apnea and other breathing disorders have been developed. These masks

18   provide seals for preventing air from escaping from the mask at the junction of the

19   mask and face. Other types of masks for gas delivery to a patient are also in common

20   use.

21   Measuring air flows to a patient has been accomplished by metering sensors in

22   the air supply connected to the mask as in patent 5.503,146 or by belts around the

23   patients chest to measure his breathing as in patent 5,131,399.

24   Some devices such as in patent 5,507,716 provide sensors combined with

25   sleep masks for covering the eyes of a patient. However there is no known example of

1   sensors built into breathing masks for monitoring or studying patients with breathing

2   disorders.

3   Currently if a patient is to be carefully monitored a plurality of electrodes or

4   sensors would have to be individually applied to the patient and wired to recording

5   equipment. The plurality of sensors and tangle of ensuing wires impede the usage of

6   such monitoring equipment. Sensors providing useful information include Electro-

7   encephalogram (EEG), electromyography (EMG), electro-oculogram (EOG), electro-

8   cardiogram (ECG), Pulse Transit Time (PTT), gas flow sensors, temperature sensors,

9   microphones, blood oxygen meters, blood pressure sensors, pulse sensors, patient

10 movement, position, light, activity sensors, mask leakage, mask pressure, eye

11 movement by polyvinylidene flouride-(PVD) or Piezo, and other means of gathering

12 data about the patient or his environment.

13   It is very inconvenient for the patient and the health care worker to attach a

14 series of different devices to a patient to monitor a plurality of different parameters

15 simultaneously. Therefore a single device for easily measuring a plurality of

16 parameters is desired.

17

18   Summary of the Invention

19

20   The invention relates to providing sensors in breathing masks to make it easy

21 to monitor a patient. The mask has a soft pliable seal material around its perimeter in

22 contact with the patient's face to form a secure seal therewith. Sensors may be

23 recessed into the soft pliable seal material at the surface for contact with the skin of

24 the user when the mask is applied to the user's face. The wiring for the sensors may

25 be inside the soft pliable seal material insulating the wires from damage during use of

1   the mask. Many sensors can be incorporated into the mask. Sensors may be placed on

2   the perimeter or on other portions of the mask not in contact with the skin. Sensors

3   may also be placed on straps or caps used in conjunction with the masks or on other

4   devices used with the mask.

5   Monitoring of patients with sleep disorders, breathing disorders or for

6   anesthesia is made easier and more convenient for the patient and for the health care

7   provider since all the sensors needed are built into a mask which is easily and quickly

8   placed on the patient with all the wiring to the sensors integral with the mask and

9   accessed by a single plug.

10   The types of sensors on or in the mask and straps or caps connected to the

11   mask include but are not limited to oximetery sensors, patient position sensors, eye

12   movement sensors, leak detection sensors, EEG, EMG, EOG, ECG, PTT,

13   microphones, pulse, blood pressure, oxygen saturation, temperature, movement

14   sensors, position sensors, light sensors, leak detection sensors and gas delivery

15   sensors.

16   Connections to outside sources of gases delivered to the mask are by a gas

17   nozzle hook up on the mask. A connection to electrical power and data output cables

18   are by a plug in to a cable connecting to the mask. Alternatively batteries in the mask

19   and telemetry equipment in the mask can provide power and transmission of the data

20   to a microprocessor or computer. For portability the microprocessor can be attached

21   to the mask or be carried by the patient. Similarly a bottle of gas may be connected to

22   the mask and carried by the patient to allow mobility of the patient while wearing the

23   mask.

24   Unique applications for the bio-mask include the capability to apply

25   anesthesia-depth monitoring while administering anesthesia gas to a subject. The

1   ability to monitor the patient non-invasively with the bio-mask while at the same time

2   administering the anesthesia gas to the patient provides a bio-feedback function for

3   immediate and responsive anesthesia depth of the subject. The bio-mask can be used

4   to determine the subject's sleep state by applying standard sleep staging criteria, such

5   as that of R&K rules and/or the application of diagnostic techniques which analyze a

6   number of EEG signals, such as Bispectral Analysis. The invention is unique in its

7   capability to apply such analysis with the minimal-invasive application of a subject

8   breathing mask.

9   R&K rules refer to "A Manual of Standardized Terminology, Technicques and

10   Scoring System for Sleep Stages of Human Subject" by Rechtschaffen and Anothony

11   Kales, Editors 1968 which is hereby made a part hereof and incorporated herein by

12   reference.

13

14   Objects of the Invention

15

16   It is an object of the invention to monitor a patient.

17   It is an object of the invention to provide data needed to help treat a patient.

18   It is an object of the invention to provide sensors for monitoring a patient in or

19   on a breathing mask or on its associated parts.

20   It is an object of the invention to regulate the flow of gasses to a patient based

21   on the data obtained from monitoring the patient.

22   It is an object of the invention to diagnose the patient based on data obtained

23   from monitoring the patient.

24   It is an object of the invention to easily and quickly apply all the sensors

25   needed for monitoring the patient.

1   Other objects, advantages and novel features of the present invention will

2   become apparent from the following detailed description of the invention when

3   considered in conjunction with the accompanying drawing.

4

5   Brief Description of the Drawings

6

7   Fig. 1 shows a schematic view of the zones for sensors on the inside surface of a soft

8   pliable material on the perimeter of the breathing mask.

9   Fig. 2 shows a view of the sensors and wiring inside the soft pliable material on the

10   perimeter of the breathing mask.

11   Fig. 3 shows a side schematic view of the sensors and the wiring inside of the soft

12   pliable material on the perimeter of the breathing mask.

13   Fig 4 shows a side schematic view of the straps connected to the mask with sensors

14   embedded in the straps and the mask.

15   Fig. 5 shows a schematic view of the sensor zones on the perimeter of the breathing

16   mask.

17   Fig. 6 shows a schematic view of the sensors on the inside surface of a breathing

18   mask.

19   Fig. 7 shows a side schematic view of the mask with sensors on the surface of the

20   mask.

21

22   Description of the Preferred Embodiments

23

24   Fig. 1 shows the inside of mask 10 including the perimeter surface 12 which

25   contacts the patient's face. The perimeter surface 12 has a plurality of zones 20. Each

1   zone 20 having a sensor 25 in a recess 29 for measuring a parameter of the patient to

2   be monitored or other data such as gas leakage. Other sensors 26 are on the mask 10

3   but not in contact with the patient's skin. These sensors 26 measure patient data or

4   related data such as ambient light, gas pressure in the mask or ambient temperature.

5   The mask 10 has a gas connector 14 for connecting a hose 32 to provide a gas to the

6   mask 10 and a mask interface connector 16 for plugging in a cable 30 for a power

7   supply and for data transmission.

8   In some embodiments of the invention the sensors 25 do not require an outside

9   source of power as the sensors such as heat sensors and light sensors generate current.

10   The mask perimeter surface 12 is preferably made out of a soft pliable

11   material such as silicone rubber for making a good sealing contact with the face of the

12   patient to prevent gas leakage. The material should be soft and pliable enough to

13   follow the contours of the face. The perimeter surface preferably has recesses 29 on

14   the surface for the insertion of sensors 25 so that the sensors can make contact with

15   the patient's skin when the mask is pressed against the patient's face.

16   As seen in Fig. 3 a sensor or electrode 25 attachment to the mask 10 preferably

17   utilizes a rubber compound 28 such as silicon or other food grade type rubber

18   embedded with carbon or other conductive materials for electrical contact of skin to

19   the mask. As shown in Fig. 2 the recesses 29 are large enough to have room to make

20   electrical connections to leads 27, which are buried in the soft pliable material under

21   the perimeter surface 12. The leads 27 are thus protected from damage and electrically

22   insulated. Preferably the sensors 25 will plug into the leads 27 or printed circuits in

23   the recesses 29. The leads 27 are preferably on printed circuits embedded in the mask

24   or fine wires embedded in the mask and connect the sensors 25 to the mask interface

25   connector 16.

1   Fig. 5 shows conductive material 40 on the surface in zones 20, such as carbon

2   embedded silicon, can be used on the surface of the perimeter 12 of mask 10 in

3   separate zones 20 to conduct the electrical surface energy from the patient's face. The

4   conductive material 40 is preferably moisture activated to improve the its electrical

5   conductivity when in contact with the skin. The conductive material 40 may be

6   applied for all electrode 25 contacts in all zones 20. Alternatively electrodes 25 may

7   directly contact the patients face. The electrodes may also be inside of the soft pliable

8   material on the perimeter 12 of the mask 10.

9   Fig. 4 shows a side view of the mask 10 and straps 35 used to keep the mask

10   in place on a patient. The straps 35 have sensors 25 connected to leads 27, which

11   connect the sensors to the mask interface connector 16 and to cable 30 for

12   transmitting data to a computer or other device. The sensors 25 in the straps 35 may

13   be electro-encephalogram EEG sensors for measuring brain waves. The straps 35 may

14   be replaced with a cap having sensors therein. Alternatively a chin strap 37 may be

15   used having sensors 25.

16   Fig. 5 shows an example of the types of sensors 25 used in zones 20 around

17   the perimeter of the mask 10. Physiological signals from a patient's skin potential are

18   detected by sensors in the zones 20 around perimeter 12 of mask 10. Conductive

19   electrode paste 40 may be used to improve the electrical contact between the sensors

20   25 and the surface of the skin. The conductive paste 40 can assist in reducing the

21   impedance between the face and the electrical output from the sensors 25 in zones 20.

22   The conductive paste 40 may also assist in preventing gas leaks.

23   As an example of a mask sensor layout the following sensors and their

24   functions are described. However many other types of sensors and arrangements of

25   the sensors are possible.

1   Zone 50 is an electro-oculogram (EOG) to obtain electrical eye movement

2   reference signals from over the bridge of the nose.

3   Zone 51 is an EOG to detect electrical eye movement signals for the inner left

4   eye and zone 61 is designated for electrical eye movement signals for the inner right

5   eye. Eye movement data is related to stages of sleep such as rapid eye movement

6   REM, which indicates a deep sleep state and dreaming.

7   Zone 52 is designated for an EOG to detect electrical eye movement signals

8   for the outer left eye and zone 62 is designated for electrical eye movement signals for

9   the outer right eye.

10   Zone 53 is designated for electro-myography (EMG) to detect electrical

11   signals from muscle contractions in the upper left chin. Zone 63 is correspondingly

12   for the upper right chin. Zones 54 and 64 are for the lower left and lower right chin

13   respectively. The amplitude of the chin signals is proportional to the relaxation state

14   and subsequent sleep state of the patient.

15   Zone 55 is the EMG for the upper left lip, giving information about sleep

16   stages. It is proportional to the relaxation and sleep states of the patient. Zone 65 is the

17   EMG for the upper right lip.

18   Zone 56 is the EMG for the left nasal inner mask it also provides signals for

19   the lip movements and is proportional to the relaxation and sleep states of the patient.

20   Similarly zone 66 is for the right nasal inner mask EMG.

21   Zones 57 and 67 are for the oral left and oral right outer mask EMG signals

22   which are also proportional to the relaxation and sleep states of the patient.

23   Zone 70 is for pressure sensor ports for airflow determination.

24   Microphone 80 on the mask detects the patients breathing or snoring sounds.

1   Fig. 6 shows an alternate embodiment where two sensors 58 and 68 are used

2   to find the patient's electrocardiogram ECG. This data is also useful for monitoring a

3   patient. The patient's heart functions provide a lot of useful data about the patient's

4   condition. Pulse Transit Time (PTT) is the time it takes ECG pulses to travel from the

5   heart to a sensor such as a sensor placed on the head, on a finger tip, or on the ear.

6   PTT sensors can be in the mask, on sensors connected to the mask, or sensors used in

7   conjunction with the mask. PTT measurements are used to determine patient arousals

8   and qualitative blood pressure variation.

9   Thermal sensor 81 is used on the inside surface of the mask to detect nasal

10   breathing. Thermal sensor 82 is used on the outside surface of the mask to detect oral

11   breathing. The thermal sensitivity of the sensors 81 and 82 on the surface of the mask

12   10 opposite the nose or mouth indicates if the patient is breathing through his nose or

13   mouth. The thermal sensors 81, 82 may alternatively be placed on the inside of the

14   mask 10, on the outside of the mask10, or inside of the material of mask 10 for

15   detecting breathing. The thermal sensors 81, 82 may be a thermistor material, a

16   thermocouple material or any other temperature sensitive material. The thermal

17   sensors 81, 82 may be coatings on the inside of the mask, the outside of the mask or in

18   the mask. The thermal sensors 81, 82 detect heat, which is proportional to the amount

19   of breathing.

20   It is important to detect oral breathing for undetected or partially undetected

21   oral breathing effects the integrity of the patient breathing gas breath monitoring and

22   subsequently compromises the idea gas delivery to the patient. It is important to detect

23   mouth breathing to assist in diagnosis of sleep disordered breathing. Further, control

24   of a mask nasal ventilation is effected by mouth breathing.

1   A pressure sensor 84 measures the pressure inside of the mask to indicate if

2   there is positive pressure inside of the mask and how much. A pressure drop may

3   indicate a leak.

4   A surface reflective oximetry sensor 85 on the inside of the mask detects the

5   patients pulse rate and oxygen saturation.

6   A surface blood pressure sensor 90 on the perimeter 12 of the mask 10 in

7   contact with the patient can be used to monitor the patients blood pressure.

8   A thermistor 91 on the perimeter 12 of the mask 10 in contact with the patient

9   can be used to monitor the patients temperature.

10   A patient recycled air detection system having a sensor 95 on the inside

11   surface of the mask detects the amount expired air from the patient remaining in the

12   mask 10. High levels of expired gas in the mask indicates the mask is not being

13   flushed out and may lead to problems if not enough fresh gas is introduced.

14   A patient back gas occurrence detector 97 in the mask hose connector 14

15   detects the amount of expired gas in the mask returning with newly delivered gas.

16   Fig. 7 shows thermal sensors 83 such as thermistors or thermocouples on the

17   inside or outside of the mask adjacent the perimeter 12. These sensors can be attached

18   to a thermally conductive material 92 around the perimeter of the mask 10.

19   Alternatively the thermally conductive material may be on portions of the perimeter.

20   This thermally sensitive material can be on the inside surface of mask 10, the outside

21   surface of mask 10 or embedded within the mask material. Detection of a temperature

22   change by thermal sensors 83 or thermal sensors 83 on thermally conductive material

23   92 correlates with mask leakage around the perimeter. The thermally sensitive

24   material may be a thermally sensitive material in the mask on the inside of the mask,

25   on the outside of the mask or on the perimeter of the mask. The thermally sensitive

1 material may be a thermistor, a thermocouple, or any other thermally sensitive

2 material.

3 Gases leaking from the mask 10 will cause a temperature change associated

4 with the thermally conductive material 92 and sensors 83 and allow a healthcare

5 specialist real-time monitoring of leak status or post monitoring status of mask

6 leakage. In some instances this can be life saving where a patient's gas delivery is

7 critical and in other cases the leakage incidence can assist in the diagnosis of a patient.

8 This assistance may be in the form of alerting a health care specialist that the gas

9 delivery was subject to leakage and this may affect patient treatment and patient

10 diagnostic conditions. In other instances the gas leakage detection can allow the gas

11 delivery system to automatically compensate for the gas leakage.

12 A light sensitive resistor 86 on the outside surface of the mask 10 indicates the

13 ambient lighting conditions of the patient.

14 Position sensors 87 indicate position or activity of the patient. For example

15 these sensors show if the patient is lying down and is motionless. Such a sensor may

16 be a moving ball across switch contacts, or mercury sensor switches.

17 Body movement sensor 88 can be a PVD or piezo material or micro

18 mechanical to detect the patients body movements extent and rate to determine a

19 wake versus rest state.

20 All of the above sensors may send data by telemetry rather than by cable 30.

21 All of the above collected data may be used to monitor a patient for a variety

22 of uses including sleep studies, anesthesia and sleep apnea.

23 The data collected can be converted to a serial data stream to allow a single

24 wire to interface all the sensors. The sensors may provide data to adjust gas delivery

25 to the patient.

1   Gain and filtering adjustments to the signals may be used to condition the

2   signals close to source for optimal noise and signal performance.

3   An electrical bias to sensors such as a patient position sensors, thermal

4   conductive zones, microphones, or light dependent resistor may be applied.

5   A computer may process the data or simply store the data to from the

6   monitoring sensors in the mask or straps attached thereto. The monitoring data may be

7   used to diagnose a patient, provide feedback to machines attached to the patient,

8   increase or decrease air supplies to a patient or perform other functions.

9   An example of EEG data controlling in a bio-feedback application the delivery

10   of gas to a patient may be when a patient has a nasal ventilation device such as a

11   ventilator Continuous Positive Air Pressure (CPAP), Bi-Positive Air Pressure

12   (BIPAP), Variable Positive Air Pressure (VPAP), Sleep Linked Positive Air Pressure

13   (SPAP) and the EEG electrodes provide one of the vital signs of if the patient is

14   asleep. Gas is only applied to the mask when the patient is deemed to be asleep. This

15   function is more sophisticated, sensitive to patient comfort and commercially viable

16   than delay ramp systems used on some ventilation systems.

17   In ventilation devices that use delay ramps the user sets a time of the system

18   allocates a time and ramps up the gas pressure delivery to the patient so that the

19   application of gas does not have as much disturbing affect on the user and adversely

20   effect his ability to sleep.

21   The sensors in the mask 10 are better able to determine when the patient is

22   actually asleep before applying assisted nasal ventilation. Premature application of

23   pressure can prevent the patient from sleeping due to the added discomfort of positive

24   pressure.

1   The mask 10 may be made such that it is a sterile disposable unit for medical

2   use thus lowering costs of treatment by not needing to sterilize masks for new patients

3   and providing a more sterile treatment than reusable masks.

4   Obviously , many modifications and variations of the present invention are

5   possible in light of the above teachings. It is therefore to be understood that, within

6   the scope of the appended claims, the invention may be practiced otherwise than as

7   specifically described.

8   What is claimed is:

1

1   1.   A mask with sensors for monitoring a patient during gas delivery comprising:

2   a mask having a perimeter for contacting the face of a patient,

3   at least one sensor on the mask to sense at least one parameter indicating a

4   state of the patient,

5   leads in the mask connected to the at least one sensor for transmission of data,

6   a means for transmitting data from the mask,

7   a hose connector on the mask for attachment of a hose for delivery of gas to

8   the mask.

1

1   2.   A mask with sensors for monitoring a patient during gas delivery as in claim 1

2   wherein,

3   the means for transmitting data from the mask comprises a mask interface

4   connector for connecting the leads in the mask to a cable.

1

1   3.   A mask with sensors for monitoring a patient during gas delivery as in claim 1

2   comprising,

3   a means for providing power to the mask to operate the sensors.

1

1   4.   A mask with sensors for monitoring a patient during gas delivery as in claim 3

2   wherein,

3   the means for providing power to the mask to operate the sensors comprises a

4   mask interface connector connecting a power source lead to a lead in the mask for

5   transmitting power to a sensor and:

6   the means for transmitting data from the mask comprises a mask interface

7   connector for connecting the leads in the mask to a cable.

1   5.   A mask with sensors for monitoring a patient during gas delivery as in claim 3

2   wherein,

3   the means for providing power to the mask to operate the sensors comprises a

4   battery attached to the lead in the mask for transmitting power to a sensor and;

5   the means for transmitting data from the mask comprises a telemetry device.

1

1   6.   A mask with sensors for monitoring a patient during gas delivery as in claim 1

2   wherein,

3   the sensors on the mask are selected from the group consisting of, EEG, EMG,

4   EOG, ECG, PTT, temperature, surface blood pressure, pulse, blood oxygen level,

5   light, breathing rate, breathing volume, gas flow, nasal air flow, oral air flow,

6   position, activity sensors, mask leakage, mask pressure, eye movement, microphones,

7   gas pressure, patient recycled air detection, patient back gas and movement.

1

1   7.   A mask with sensors for monitoring a patient during gas delivery as in claim 1

2   wherein,

3   at least one sensor on the perimeter of the mask makes contact with the skin of

4   the patient for measuring a parameter.

1

1   8.   A mask with sensors for monitoring a patient during gas delivery as in claim 7

2   wherein,

3   the perimeter of the mask has a soft pliable material for contacting the face of

4   the patient.

1

1　　9.　　A mask with sensors for monitoring a patient during gas delivery as in claim 8

2　　wherein,

3　　　　　the material has at least one recess with a sensor in the recesses for contacting

4　　the skin of the patient.

1

1　　10.　　A mask with sensors for monitoring a patient during gas delivery as in claim 9

2　　wherein,

3　　　　　leads in the pliable material are connected to the at least one sensor for power

4　　and data connections therewith.

1

1　　11.　　A mask with sensors for monitoring a patient during gas delivery as in claim 8

2　　wherein,

3　　　　　a carbon embedded rubber material provides electrical contact between the

4　　sensor in the soft pliable material and the patient's skin.

1

1

1　　12.　　A mask with sensors for monitoring a patient during gas delivery as in claim 1

2　　wherein,

3　　　　　the mask has at least one strap attached to the mask to hold the mask in place.

1

1　　13.　　A mask with sensors for monitoring a patient during gas delivery as in claim 1

2　　wherein,

3　　　　　the mask has at least one strap attached to the mask to hold the mask in place

4　　and the strap has at least one sensor wired to the mask for monitoring the patient.

1

1   14.   A mask with sensors for monitoring a patient during gas delivery as in claim 1

2   wherein,

3   the mask has a cap attached to the mask to hold the mask in place.

1

1   15.   A mask with sensors for monitoring a patient during gas delivery as in claim 1

2   wherein,

3   the mask has a cap with at least one sensor attached to the cap, the sensor

4   leads on the cap connected to the leads in the mask for monitoring the patient.

1

1   16.   A mask with sensors for monitoring a patient during gas delivery as in claim

2   13 wherein,

3   the strap includes a chin strap.

1

1   17.   A mask with sensors for monitoring a patient during gas delivery as in claim 1

2   wherein,

3   at least one sensor in the chin strap for measuring chin EMG

1

1   18.   A mask with sensors for monitoring a patient during gas delivery as in claim

2   13 wherein,

3   the straps include a head strap having a sensor for measuring EEG.

1

1   19.   A mask with sensors for monitoring a patient during gas delivery as in claim

2   15 wherein,

3   the cap includes sensor for measuring EEG.

1

20.   A mask with sensors for monitoring a patient during gas delivery as in claim

13 wherein,

  the strap includes an ear strap having an oxygen saturation sensor applied to

the ear of the patient.

21.   A mask with sensors for monitoring a patient during gas delivery as in claim 1

wherein,

  a thermal sensor on a portion of the mask detects changes in temperature on

that portion of the mask.

22.   A mask with sensors for monitoring a patient during gas delivery as in claim

21 wherein,

  the mask has a thermally conductive material to which the thermal sensors are

thermally coupled.

23.   A mask with sensors for monitoring a patient during gas delivery as in claim 1

wherein,

  a thermally sensitive material on the mask proximate the patient's nose detects

temperature variations for nasal breathing detection.

24.   A mask with sensors for monitoring a patient during gas delivery as in claim 1

wherein,

  a thermally sensitive material on the mask proximate the patient's mouth

detects temperature variations for oral breathing detection.

1   25.   A mask with sensors for monitoring a patient during gas delivery as in claim 1

2   wherein,

3   a thermally sensitive material on the mask proximate mask perimeter detects

4   temperature variations for leak detection.

1

1   26.   A mask with sensors for monitoring a patient during gas delivery as in claim

2   21 wherein,

3   the thermally sensitive material comprises a thermistor.

1

1   27.   A mask with sensors for monitoring a patient during gas delivery as in claim

2   21 wherein,

3   the thermally sensitive material comprises a thermocouple.

1

1   28.   A mask with sensors for monitoring a patient during gas delivery as in claim

2   21 wherein,

3   the thermally sensitive material comprises a coating on the mask.

1

1   29.   A mask with sensors for monitoring a patient during gas delivery as in claim

2   21 wherein,

3   the thermally sensitive material portion of the mask comprises an internal

4   surface portion of the mask.

1

1.

1   30.   A mask with sensors for monitoring a patient during gas delivery as in claim

2   21 wherein,

3   the thermally sensitive material portion of the mask comprises an external

4   surface portion of the mask.

1

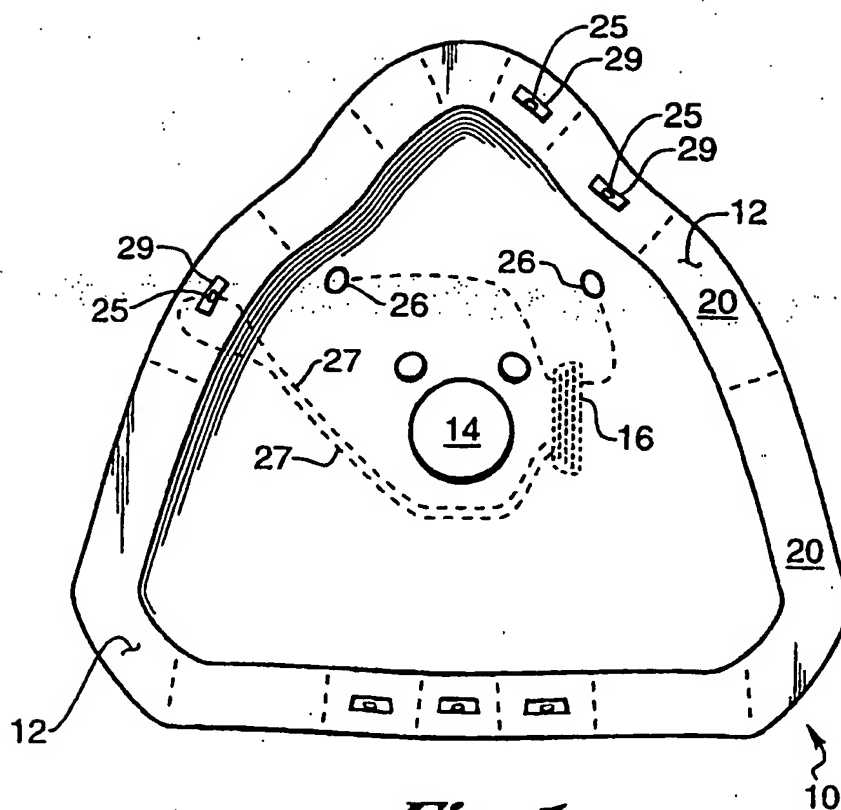1   31.   A mask with sensors for monitoring a patient during gas delivery as in claim

2   21 wherein,

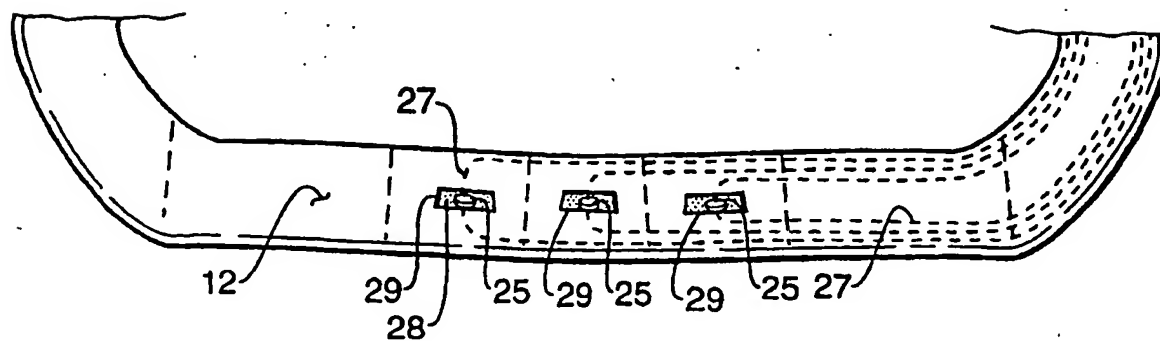3   the thermally sensitive material portion of the mask comprises a portion within
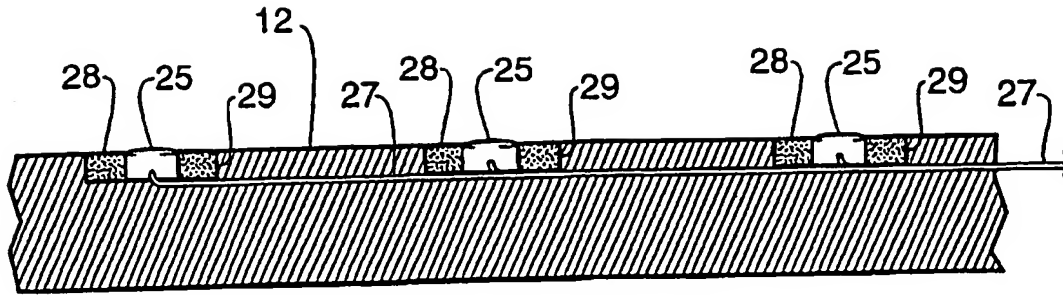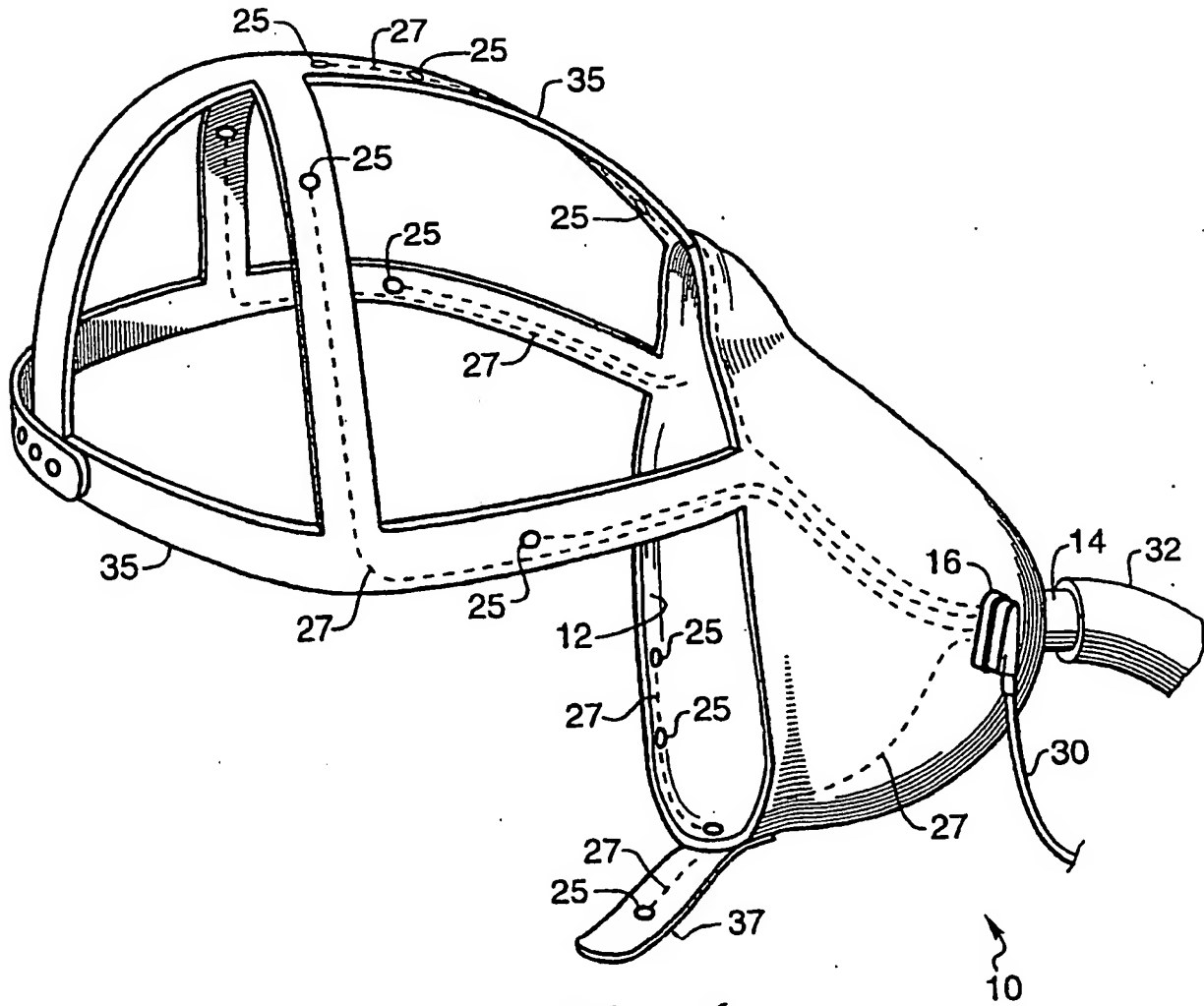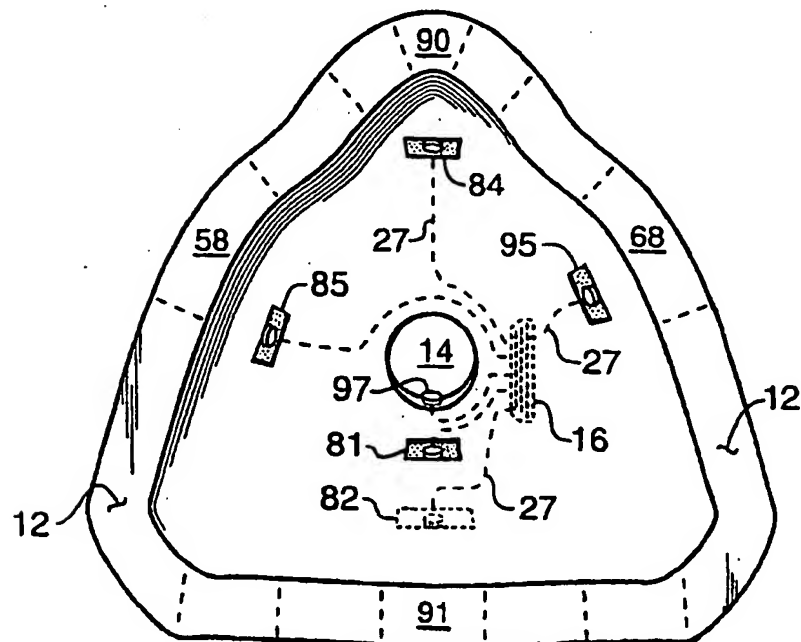
4   the mask material.

1
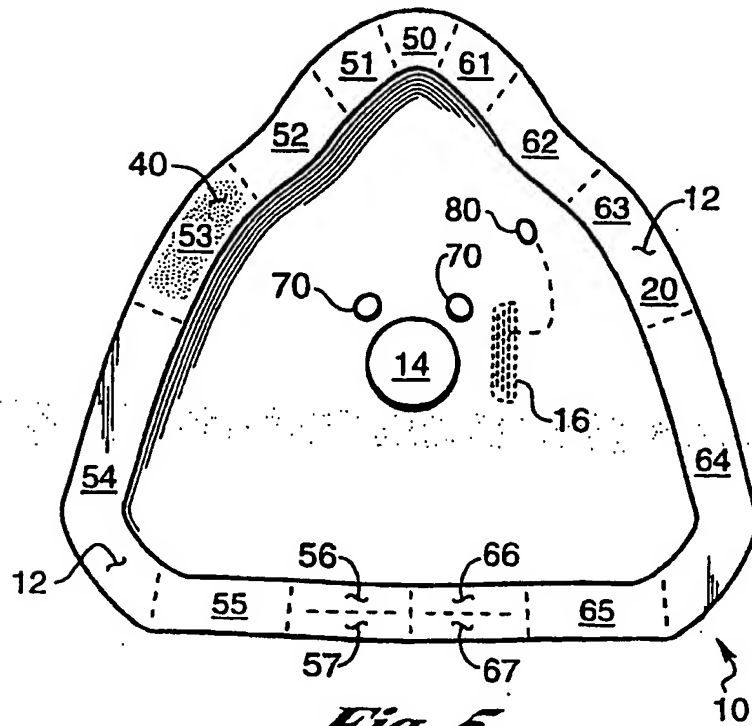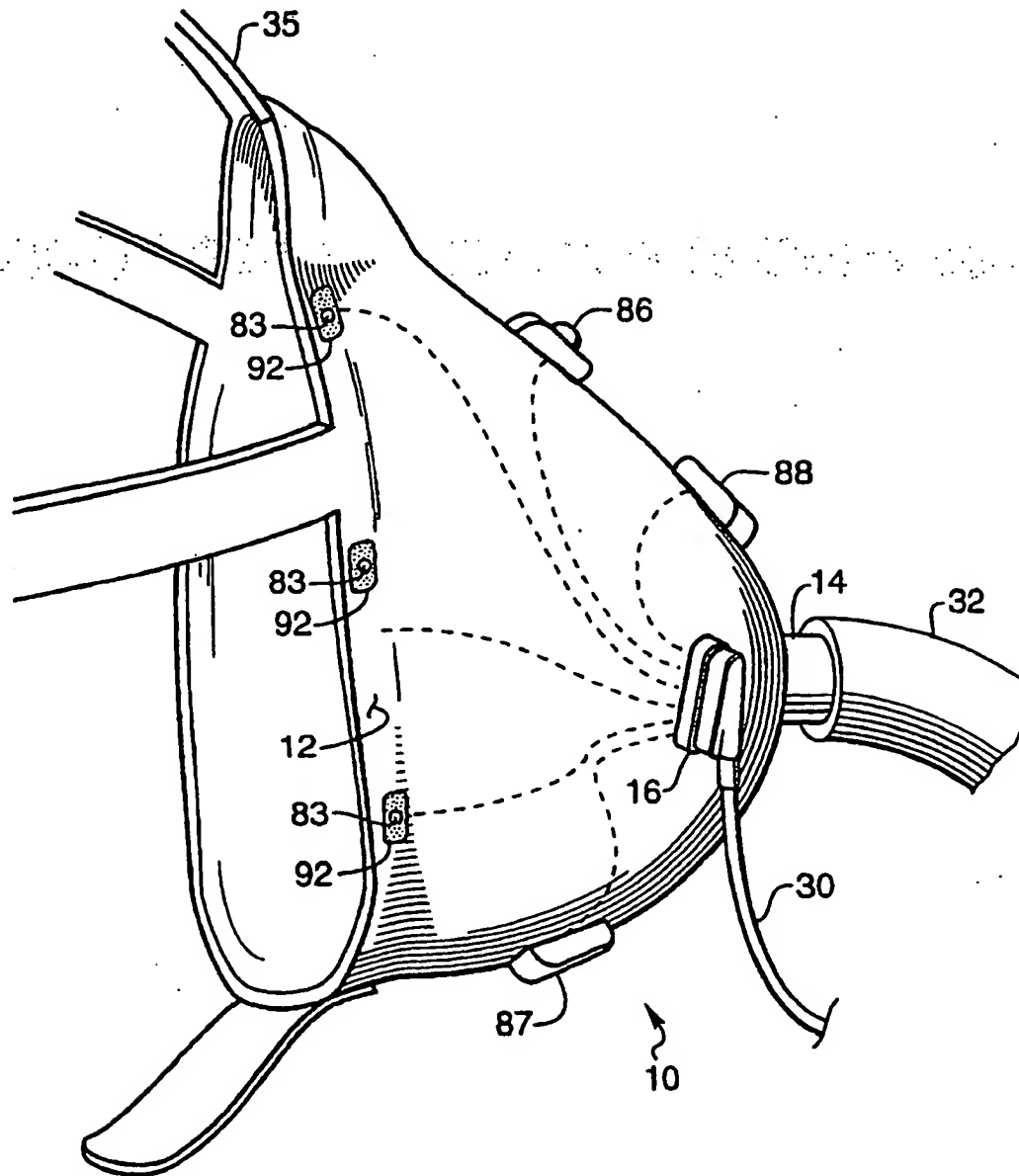
Fig. 1

Fig. 2

28 25   12   27 28 25 29   28 25   29 27
      29

Fig. 3

25   27 25   35
      25
25
25
27
35   27   25
      12 25
27   25
16 14 32
27
30
27 25
37   10

Fig. 4

Fig. 5

Fig. 6

Fig. 7

INTERNATIONAL SEARCH REPORT

A.	CLASSIFICATION OF SUBJECT MATTER

Int. Cl. [7]:   A61M 16/06, A61B 5/08

According to International Patent Classification (IPC) or to both national classification and IPC

B.	FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
Key word search

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
DWPI mask, breath, respir:, gas, oxygen, air, anaesthe:, apnea, CPAP, sensor, detect, transduc:, microphone, integral

C.	DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5860417 A (Kettl et al) 19 January 1999 Column 5, line 23 to Column 10, line 60 and Figures 1 to 6	1 to 6, 12
X	WO 97/33641 A (Beth Israel Deaconess Medical Centre, Inc) 18 September 1997 Whole document	1 to 6, 12
X	GB 2294642 A (Brain) 8 May 1996 Whole document	1, 6

[X] Further documents are listed in the continuation of Box C   [X] See patent family annex

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
28 February 2001	6 March 2001
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized officer **COLIN FITZGIBBON** Telephone No : (02) 6283 2226

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4875477 A (Waschke et al) 24 October 1989 Column 2, lines 45 to line 64	1, 6 to 8, 12

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member							
US	5860417	US	5503141						
WO	97/33641	AU	20674/97	US	5857460				
GB	2294642	CA	2162013	US	5584290				
US	4875477	DE	3724336	EP	303056	JP	1049535		

END OF ANNEX